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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,633	01/10/2002	Akio Kobayashi	111632	6574

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OLIFF & BERRIDGE, PLC  
P.O. BOX 19928  
ALEXANDRIA, VA 22320

EXAMINER

BERTOGLIO, VALARIE E

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/041,633	Applicant(s) KOBAYASHI ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

Applicant's amendment filed on 04/12/2004 has been entered. Claims 3 and 4 have been cancelled. Claims 1,5-7 and 15 have been amended. Claims 1-3 and 5-15 are pending and under consideration in the instant action.

#### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-15 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is maintained for reasons of record set forth on pages 3-7 of the previous office action mailed 01/12/2004.

Applicant's arguments have been fully considered and are not found persuasive.

Applicant argues that the specification discloses that the size of the hole bored in the cell can be about 1 to 1,000  $\mu\text{m}^2$ , which is large enough to accommodate a nucleus of an average size of 10 $\mu\text{m}$ . Applicant also argues that the rejection based on the fact that a large hole as claimed can kill or harm the nucleus is moot because the claims do not require that the cell not be harmed or killed. Applicant further argues that the specification does disclose that an onion skin epidermic cell which was irradiated with a laser, removing the cell wall, and was still alive after 24h.

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In response, as set forth on page 5 of the previous office action mailed 01/12/2004, the hole should be no more than 500 nm (refer to EP 0483847A2, page 3, lines 29-31). While the specification contemplates that the hole size could be as large as  $1,000 \mu\text{m}^2$ , it teaches boring a  $2 \mu\text{m}$  hole and does not teach how to bore a hole as large as  $1,000 \mu\text{m}^2$  without destroying the cell. Mere contemplation of the method does not overcome the state of the art demonstrating that there is an upper limit on the size of a hole that can be made in a cell. With respect to applicant's argument that the claims do not recite that the cells remain viable, one of skill in the art would not know how to use a dead cell and the specification does not teach how to use a dead cell. Specifically, claim 8 requires introduction of foreign matter into the "living cell". If the hole bored in the cell is so large that it kills the cell, then there will be no living cell into which to introduce the foreign matter. Therefore, it would require undue experimentation for one of skill in the art to carry out and use the methods claimed in a manner to achieve a hole in a cell so large as to accommodate a cellular organelle as one of skill in the art would not know how to use a dead cell. With respect to the teachings in the specification demonstrating removal of an onion skin cell wall, Applicant's argument is off point and not relevant to the rejection of the claims as they encompass boring a large hole through the cell wall.

Applicant also argues that "one skilled in the art would understand that a pulse laser beam may be used with beam expander to create an XY slit on a light path and micro projection may be carried out to the surface of the cell using a projection lens" (page 7, paragraph 3). Applicant has failed to provide any relevant art supporting this statement and whether such a procedure maintains viability in the cell so as to overcome the state of the art indicating that a "large" hole in a cell, greater than 500 nm, will kill the cell, cannot be determined.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-15 under 35 USC 112, 2<sup>nd</sup> paragraph is withdrawn in light of Applicant's amendments to the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Kwon (1997, Oncogene, Vol. 15, pages 26252631) is maintained for reasons of record set forth on page 10 of the previous office action.

Applicant argues that claim 15 depends from claim 1 and that Kwon does not recite all of the limitations of claim 1.

As set forth in the previous office action, claim 15 is a product by process claim. The claimed product is a transformed cell. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (a transformed body) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed transformed body are met by any transformed body in the prior art.

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Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spade*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01.

Kwon teaches fibroblasts transformed with oncogenic agents (page 2626, col. 1, lines 3-5) as well as spontaneously transformed cells such as HeLa cells (page 2626, col. 2, line 5).

Therefore, Kwon satisfies all of the limitations of claim 15.

The rejection of claims 1-3 and 7 under 35 USC 102(b) has been withdrawn in light of applicant's amendments to claim 1.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The previous rejections under 35 USC 103(a) are withdrawn. New rejections appear below.

1) Claims 1,2 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abela (1996, USPN 5,586,982;IDS) or Henriksen (1997, Eur. J. Physiol., Vol. 433, pages 832-841, IDS) in view of Beeh (1971, US 3,573,456) and further in view of Rink (1996, USPN 5,498,260).

Claim 1 is drawn to a method of processing a cell comprising irradiating a cell with a laser beam through an optical fiber and removing or boring an entirety of the cell thus irradiated wherein the laser is reflected and condensed through a chip of quartz glass. Claim 2 limits the laser wavelength to 500 nm or less. Claims 5 and 6 add the limitation that the quartz be coated with a metal. Claim 7 limits the laser to a YAG laser, an excimer laser, an Ar ion laser, a nitrogen excited laser, or a nitrogen laser. Claims 8-10 add the method step of introducing a foreign matter into the cell. Wherein the foreign substance is a genetic material (claim 9) or DNA (claim 10).

Abela taught applying laser energy consisting of a 355 nm YAG laser (column 7, lines 40-42) transmitted through a fiber optic bundle (col. 5, lines 45-46; Figure 2; Figure 17) to porate cells (column 4, lines 54-56) followed by introducing a genetic material following laser treatment (column 8, lines 19-22). Abela did not teach irradiating the laser through a chip of quartz glass.

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Henriksen taught using a nitrogen laser with a wavelength of 337.1 nm (page 833, col. 1, 2<sup>nd</sup> to last para.; col. 2, line 16) that is reflected and condensed (paragraph bridging pages 834-835) to ablate a portion of a plant cell wall (page 838, col. 2, para. 2), giving access to the protoplast for a patch clamp.

However, Beeh taught using quartz or fluorite to condense a laser in the UV range because quartz and fluorite are the best material operating in this wavelength range (column 3, line 64- column 4, line 9). Beeh did not teach coating the quartz with a metal.

However, Rink also taught using quartz at the tip of a laser as it is transparent, hard and heat resistant (column 3, lines 3-5) Rink also taught coating the tip with gold to reflect the laser energy (column 3, lines 6-16).

Accordingly, in view of the teachings of Beeh and of Rink, it would have been obvious for one of ordinary skill in the art, at the time the claimed invention was made, to modify the teachings of Abela by passing the laser through a chip of gold coated quartz glass to reflect and condense the laser as taught by Beeh and by Rink. One of ordinary skill in the art would have been sufficiently motivated to make such a modification as it was an art-recognized goal to design a laser that can condense and reflect energy in the UV range and be resistant to the resulting heat.

Thus, the claimed invention, as a whole, is clearly prima facie obvious in the absence of evidence to the contrary.

2) Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Abela (1996, USPN 5,586,982;IDS) or Henriksen (1997, Eur. J. Physiol., Vol. 433, pages 832-841, IDS) in



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view of Beeh (1971, US 3,573,456) and further in view of Rink (1996, USPN 5,498,260) as applied to claims 1,2 and 5-10 above, and further in view of Brauer (1997, USPN 5,951,543) and Matsuura (2000, USPN 6,141,476).

Claim 11 depends from claim 1, which is drawn to a method of processing a cell comprising irradiating a cell with a laser beam through an optical fiber and removing or boring an entirety of the cell thus irradiated wherein the laser is reflected and condensed through a chip of quartz glass. Claim 11 adds the limitation that the quartz fiber is hollow.

As set forth, Abela, taken with Beeh and Rink taught applying laser energy to a cell wherein the laser is transmitted through a fiber optic waveguide, which further comprises a chip of quartz glass for reflection and condensing as required by claim 1. Abela did not teach that the quartz fiber used was hollow.

However, at the time the claimed invention was made, Brauer taught using a flexible, hollow waveguide (Abstract, line 2; col. 4, lines 40-48) to introduce a laser in vivo because the hollow waveguide offers greater flexibility for in vivo manipulation (Abstract; col. 5, line 11; col. 7, lines 1-6). Furthermore, Matsuura taught making a flexible hollow waveguide for transmitting ultraviolet laser radiation with low attenuation (abstract; col. 1, lines 29-32 and 47-51). Matsuura taught that a hollow waveguide is the best of delivery media for ultraviolet light (column 1, line 66-column 2, line 4)

Accordingly, it would have been obvious at the time the claimed invention was made, to use the laser of Abela using the hollow fiber optic waveguide of Brauer or of Matsuura. One of ordinary skill in the art would have been sufficiently motivated to replace the solid quartz waveguide of Abela with the hollow waveguide of Brauer or of Matsuura, because the hollow

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waveguide offers greater flexibility (Brauer, Abstract; col. 5, line 11; col. 7, lines 1-6; Matsuura, col. 2, lines 60-65) than a solid waveguide, and because the hollow waveguide is the best media for delivering a UV laser (Matsuura, column 1, line 66-column 2, line 4).

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

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*Conclusion*

**No claim is allowed.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725.

The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Deborah Crouch*

DEBORAH CROUCH  
PRIMARY EXAMINER  
GROUP 1800/630

Valarie Bertoglio  
Examiner  
Art Unit 1632